IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of
ZOHOUNGBOGBO, Mathias C.

Serial No. 09/982,554 Group Art Unit: 1617
Filed: October 18, 2001 Examiner: San-Ming Hui

For: DIETETIC FOOD COMPOSITION AND DIETETIC METHOD USING SUCH COMPOSITION

DECLARATION UNDER 37 CFR § 1.132

Honorable Commissioner
of Patent and Trademarks
Washington, D.C. 20231

Sir:

I, ZOHOUNGBOGBO, Mathias C., a citizen of Italy, hereby declare and state:

1. I was born on the 24th of February, 1941 in Ouidah, in the Republic of Benin, in Western Africa.

2. I arrived in Italy on the 20th of November 1962 and I enrolled in the School of Medicine and Surgery of the University of Siena. I completed my university studies in Turin, where I graduated with flying colours on the 24th of July 1968. I am specialised in General Surgery (24 July 1973), in Clinical Oncology (5 July 1976) and Emergency Surgery and Emergency Response (22 June 1979) achieving top marks in all three specialities. At the end of the '70s, I directed my efforts to

what was soon to become my main professional activity: the study of obesity and leanness.

In 1977 I became the Clinical Director of the Centro di Salute in Rivalta di Torino, a general surgery health centre providing all specialised treatments covered by the National Health Service.

I resigned from my position as general practitioner, directing my efforts to nutritional studies. In addition to my practices in Milan and Bari, inaugurated in 1983, I opened three new medical practices in Verona (1989), Bologna (1994) and Rome (2000).

In the early '90s, I concentrated on the study of low-sugar foods.

4. I am the inventor of the above referenced patent application and I am familiar with the references applied in the Office Action mailed January 15, 2003.

5. It is well known in the art as well as largely diffused by all the mass media since a log time that obesity or even overweight in persons is an important associated cause of cardiovascular and metabolic diseases, such as myocardial infarction, stroke, type II diabetes, etc.

The above consequences for health of individuals and for overall health costs have become so critical that developed nations as developing nations consider them one of the most diffused cause of mortality all over the world.

For the above reasons, I decided many years ago to start a battle against obesity and, consequently, I focused my attention on food regimens in humans.

The most common measures adopted to combat obesity consist of diets based on low-calories, low-fat regimes or the widely recommended "Mediterranean diet".

However, low-calories and low-fat regimes impose to an individual a very strict regime based on the elimination or a

strong limitation of a large number of foods, therefore subjecting said individual to suffer the deprivation of some foodstuffs. In addition, said regimens have been demonstrated to have only temporary effects on reducing body weight and they result in general weakening of the body.

The "Mediterranean diet" is indeed suitable for maintaining the right weight in individuals who are engaged in vigorous physical activity.

A further regimen or diet known since many years is called by the dieticians "ketogenic diet".

A "ketogenic diet" was introduced for the first time by Mr. Atkins in 1972 and it comes out from the findings that the carbohydrates are the real cause of the storing up of lipids in individuals. Therefore, the total elimination of all foodstuffs containing carbohydrates and the substitution with foodstuffs containing proteins and fibres brings to a considerable loss of weight.

Even if this kind of diet has been demonstrated to be really effective, unfortunately it is also well known that it can cause several side-effects such as, hypercholosterolemia, hypertryglyceridemia, hyperuricemia, hyperglycemia, hepatic-pancreatic alterations, mental disorders.

Accordingly, I studied for several years a solution to this problem in order to render the "ketogenic diet" suitable for individuals who desire to recover and to maintain ideal weight and which avoids the above mentioned side-effects.

6. To this aim, my idea was to find out a treatment to these side-effects so that individuals could adopt the "ketogenic diet", which has been demonstrated to give good results, without having to worry about possible decompensations of physiological values.

It is known that there are several single compounds each of which is useful to control a particular physiological value which is altered in humans, as disclosed in the prior art cited in the above Office Action.

Starting from this common general knowledge, I analysed the clinical situation of my patients who were subjected to a "ketogenic diet" and my idea was just to try to adapt the pharmacology of said single compounds in a way which could result advantageous to the clinical situation of a "ketogenic diet".

After several attempts, I was able to provide a composition of some of them which could allow the simultaneous administration of single compounds so that the above disadvantages could have been overcome.

In addition, I surprisingly found that the effect of my composition was so good that the hematic values of my patients subjected to the "ketogenic diet" were in the normal value range, i.e. the value range of healthy individuals, in a relatively short time after the treatment (two months).

In the following table, I report a comparative example wherein the values of a patient before my treatment have been compared with the values of said patient after the treatment with my composition according to the Example 8 disclosed in my invention. Furthermore, the value range in parenthesis is the normal value range of healthy individuals.

TABLE I

Patient's parameters	Values before treatment	Values After Treatment with the composition of Example 8
Cholesterol	370	220 (up to 260 mg/dl)
Trygliceride s	720	125 (70-170 mg/dl)
Glicemia	120	95 (90-110 g/ml)

Patient's parameters	Values before treatment	Values After Treatment with the composition of Example 8
Uric acid	8	5 (up to 7)
transaminases	30	12 (up to 24)
fibrinogen	450	400 (200-400 mg/l)

As can be clearly seen, all the values fall within the healthy individual range.

In particular, it is to be noticed that the last parameter taken into consideration (fibrinogen) has very surprisingly been demonstrated to fall into the normal value.

It is known that said parameter is not strictly correlated with obesity, however it has been seen that, probably due to inflammatory situation at the liver caused by obesity, fibrinogen value can in any case be altered.

Therefore, once again my composition has been demonstrated to be effective also against such kind of alteration just thanks to an advantageous and unpredictable synergic effect never realized before in this state of the art.

In view of the above, it is to be noticed that through the reading of the prior art documents cited in the above Office Action I did not find any suggestion that the single compounds of my composition can be given in combination to treat the side-effects of a "ketogenic diet". On the contrary, I had to perform several attempts to find out the effective combination of my invention.

In fact, it is well known to the physicians that drugs available on the market are composed by at most two kinds of active ingredients. Nobody has demonstrated a surprising synergic effect of a composition as the one of my invention comprising more than two active ingredients.

From the above consideration, it can be understood that none of said prior art documents show that all the physiological values of patients under "ketogenic diet" can be recurred or maintained as normal values, i.e. values of healthy individuals, using the composition of my invention.

Furthermore, I noticed that this way of treating patients could bring to an additional advantage consisting of avoiding to control patients who have to bring a great number of single drugs or patients themselves who have to remember that they have to bring lots of single drugs during all the day.

As a consequence, my composition provides the further advantage to render available a simple or "user-friendly" method to treat the side effects of a ketogenic diet.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

28 May 2003

(date)

(signature)